510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name:	C. R. Bard, Inc. Bard Urological Division
Address:	13183 Harland Dr. Covington, GA 30014
Contact Person:	Julie J. Bassett
Contact Person's Telephone Number:	678-342-4921
Contact Person's Fax:	770-788-5517
Date of Preparation:	March 9, 2006

B. DEVICE NAME:

Trade Name(s):	Bard Align™ Urethral Support System
Common/Usual Name:	Urethral Sling; Surgical Mesh
Classification Names:	79 OTN– Mesh, Surgical, Polymeric; CFR Reference: 21 CFR 878.3300, Surgical mesh

C. PREDICATE DEVICE NAME:

Trade Name(s): Uretex® TO Trans-Obturator Urethral Support System

D. DEVICE DESCRIPTION:

The Align™ Urethral Support System includes a sterile, single use permanent implant that provides strong, stable support for the urethra in patients with stress urinary incontinence. The mesh consists of a knitted, open porosity, monofilament, polypropylene mesh strip. The open porosity of the mesh design and large pore sizes allows for macrophage penetration and tissue ingrowth to promote the creation of a permanent support for the urethra. The knitted polypropylene mesh is made from a small fiber diameter which creates a soft and pliable material.

Several configurations of this device will be offered, including retropubic, suprapubic, and transobturator, which are used to implant the device.

The principles of operation and fundamental scientific technology have not changed from the predicate.

E. INTENDED USE:

The Align™ Urethral Support System is indicated for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The intended use has not changed from the predicate (K041176).

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The subject device, the Align™ Urethral Support System, has the same intended use, general design and fundamental scientific technology as the predicate device (K041176).

G. PERFORMANCE DATA SUMMARY:

The appropriate testing, including guidance testing, to determine substantial equivalence of the Align™ Urethral Support System was conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 28 2012

C.R. Bard, Inc.
% Ms. Julie J. Bassett, RAC
Regulatory Affairs Specialist
13183 Harland Drive
COVINGTON GA 30014

Re: K070073
Trade/Device Name: Align™ Urethral Support System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: January 5, 2007
Received: January 8, 2007

Dear Ms. Bassett:

This letter corrects our substantially equivalent letter of March 21, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K070073

1.3 Indications for Use Statement

510(k) Number (if known): _____

Device Name: Align™ Urethral Support System

Indications for Use:

The Align™ Urethral Support System is indicated for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Recommended Format 11/13/2003)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices
510(k) Number K070073

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